

REMARKS

Claims 1-19 were previously pending in this application. By this amendment, Applicant is canceling claims 20-23 without prejudice or disclaimer. Claims 7 and 12-19 have been withdrawn as a result of a Restriction Requirement and Species Election. Claim 1 has been amended. As a result claims 1-19 are pending with claims 1-6 and 8-11 subject to examination with claim 1 being independent. No new matter has been added.

Sequence Compliance

The Office Action of February 18, 2004 stated that the substitute sheets previously submitted were not in compliance with the Sequence Rules. Replacement paragraphs have been provided to comply with the Sequence Rules.

Oath/Declaration

The previously submitted Declaration was found to be defective in that it contained non-initialed and non-dated alterations. A new Declaration in compliance with 37 C.F.R. 1.67(a) has been filed herewith.

Rejections Under 35 U.S.C. §112

Claims 1-6 and 8-11 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner has found that the specification fails to describe the entire genus of proteins that are encompassed by these claims. Applicants disagree.

The Office Action states that because the specification describes only one molecular embodiment, that it fails to teach or describe any other molecular embodiments. To comply with the written description requirement of 35 U.S.C. §112, it is sufficient that the specification convey clearly to those skilled in the art the information that the applicant has invented and specific subject matter later claimed. See *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976). Furthermore, the burden is on the Patent Office to demonstrate that the Applicant has failed to comply with the written description requirement. Applicants fail to see where the Office has met

its burden of showing a lack of compliance with a written description requirement. The Office Action states that the Application fails to comply with the first paragraph of §112 because there is a “lack of relevant identifying characteristics.” Applicants believe, however, that when viewed by one skilled in the art, there is adequate written description in the application to show that the inventors were in possession of the claimed invention at the time of filing. For example, see the present application at page 4, line 11 to page 5, line 20. Additional examples are provided on pages 8-11, specifically, for example, at page 8, lines 29-31 and page 11, lines 13-18. Withdrawal of the rejection is respectfully requested.

Claim 5 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Office Action finds that claim 5 is vague and indefinite insofar as it employs the term “huntingtin” as a limitation because this term is used without reference to a precise amino acid sequence identified by a SEQ ID NO. or without identifying the property or combination of properties which is unique to and, there, definitive of a “huntingtin.” Applicants disagree.

The term “huntingtin” is well known to those skilled in the art. The definiteness of this term, and thus the claim, should be analyzed in light of the instant disclosure, the teachings of the prior art and the claim interpretation of one possessing ordinary skill in the art. See e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F2d 1367 (Fed. Cir. 1986).

As described in the Huntington’s Disease Collaborative Research Group (HDCRG), *Cell*, 72, 971-983 (1983), a copy of which was submitted with the previous response, the term “huntingtin” is used to designate a specific gene, IT15, and is characterized in that it has an expected molecular weight of approximately 348 kD and reports a specific designated polymorphic (CAG)_n trinucleotide repeat which varies in length. The encoded protein exhibits polyglutamine repeats of varying length. Thus, one skilled in the art would know that “huntingtin” refers to a defined gene and its protein product with a defined polymorphic site and could easily determine whether or not a specific peptide or polypeptide is included in the term “huntingtin.” Thus, it is clear to one skilled in the art what is and is not included within the scope of claim 5.

Claims 1-6 and 8-11 have been separately rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement because the Office believes that the claims contain subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Office has found that the Applicants failed to point to support for the amendment to claim 1 that was filed on December 31, 2003.

By this Amendment, Applicants have amended claim 1 to clarify the amendment that was made under Article 34 of the PCT during the pendency of the international application. Support for the amendment can be found, for example, at page 4, lines 34-37 of the application. Withdrawal of the rejection is respectfully requested.

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CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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